IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Douglas HOVEY et al.
Title:	NOVEL FLUTICASONE FORMULATIONS
Appl. No.:	10/768,194
Filing Date:	2/2/2004
Examiner:	Andriae M. HOLT
Art Unit:	1616
Confirmation Number:	3657

REPLY BRIEF

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Sir:

Under the provisions of 37 C.F.R. § 41.39, this Reply Brief is submitted in response to the Examiner's Answer dated July 8, 2010. Although Appellants believe that no fee is required, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 19-0741.

REAL PARTY IN INTEREST

The real party in interest in this appeal is Elan Pharma International Ltd., which is the assignee of the present application as recorded at Reel/Frame numbers 015491/0685.

RELATED APPEALS AND INTERFERENCES

No related appeals or interferences are pending.

In the Examiner's Answer, the Examiner stated that Application No. 10/035,324, for "Sterile Filtered Nanoparticulate Formulations of Budesonide and Beclomethasone Having Tyloxapol as a Surface Stabilizer," currently on appeal, should be identified as a "related appeal" to the present application. Appellants respectfully disagree.

Application No. 10/035,324, filed on 1/4/2002, does not claim priority to any earlier filed application. (PCT Application No. PCT/US2002/041768, filed on 12/31/2002, claims priority benefit of Application No. 10/035,324.) In contrast, the present application, for "Novel Fluticasone Formulations," claims benefit of Provisional Application No. 60/444,626, filed on 2/4/2003. Thus, Application Nos. 10/035,324 and 10/768,194 do not share any common priority document.

Moreover, the pending claims of the two applications are directed to completely different subject matter: (1) the claims of the present application are directed to sterile filterable nanoparticulate fluticasone compositions; (2) while the claims in Application No. 10/035,324 are directed to sterile filterable nanoparticulate compositions comprising beclomethasone and budesonide and the specific surface stabilizer, tyloxapol. Thus, the claims of the two applications are directed to different active agents, and the claims of Application No. 10/035,324 are additionally limited to a specific surface stabilizer (tyloxapol) while the claims of the present application do not contain such a limitation.

In sum, Application Nos. 10/035,324 and 10/768,194 are not "related" in that they do not share any common priority document, and the two applications are not "related" by subject matter. Thus, the appeals in both applications are not "related".

STATUS OF CLAIMS

Claims 1-16, 18, 25-26, 45-46, 62-63, 68 and 82-99 are cancelled. Pending claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are finally rejected, and are the subject of this appeal. The pending claims are presented in Appendix A of this Brief.

STATUS OF AMENDMENTS

No claim amendments were made in response to the Office Action issued on April 1, 2009. No other amendments or submissions are pending in the application.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent claims 17, 22, 23, 39 and 60 are to be argued in the brief. The relevant citation to the specification is shown in the parentheses below.

Independent claim 17 reads as follows:

17. A sterile filterable **{p. 10, ll. 20-21}** dispersion **{p. 11, ll. 25-26}** comprising:

(a) an aqueous dispersion medium **{p. 35, ll. 14-21}**;

(b) fluticasone particles sufficiently small to pass through a 0.2μm filter **{p. 20, ll. 7-9}**, and have a phase selected from the group consisting of a crystalline phase, an amorphous phase, and a semi-crystalline phase **{p. 29, ll. 11-12}**; and

(c) at least one surface stabilizer adsorbed on the surface of the fluticasone particles **{p. 28, ll. 12-13}**,

wherein the dispersion is sterilized by filtration through a 0.2 μm filter **{p. 20, ll. 7-9}**.

Independent claim 22 reads as follows:

22. A sterile filterable **{p. 10, ll. 20-21}** fluticasone composition comprising:

(a) particles of fluticasone or a salt thereof **{p. 29, ll. 5-6}**, wherein at least 99.9% of the fluticasone particles have a particle size of less than 200 nm **{p. 20, ll. 3-4}**; and

(b) tyloxapol as a surface stabilizer **{p. 29, ll. 24-25}**,

wherein the composition is sterilized by filtration through a 0.2 μm filter **{p. 20, ll. 7-9}**.

Independent claim 23 reads as follows:

23. A nanoparticulate fluticasone composition **{p. 11, ll. 15-16}** comprising:

(a) particles of fluticasone or a salt thereof **{p. 29, ll. 5-6}**, wherein the fluticasone particles have an effective average particle size of less than 150 nm **{p. 8, ll. 16-18; p. 19, ll. 23-29; p. 32, l. 25}**; and

(b) at least one surface stabilizer adsorbed on the surface of the fluticasone particles **{p. 28, ll. 12-13}**,

wherein the composition is sterilized by filtration **{p. 10, ll. 20-21}** through a 0.2μm filter **{p. 20, ll. 7-9}**.

Independent claim 39 reads as follows:

39. A method of making a fluticasone composition **{p. 10, ll. 25-26}** comprising:

contacting fluticasone or a salt thereof with at least one surface stabilizer for a time and under conditions sufficient to provide a particulate fluticasone composition comprising-particles of fluticasone **{p. 10, ll. 26-28}** having an effective average particle size of less than 150 nm **{p. 8, ll. 16-18; p. 19, ll. 23-29; p. 32, l. 25}**; and

passing the particulate fluticasone composition through a 0.2μm filter **{p. 20, ll. 7-9}** to sterilize the particulate fluticasone composition **{p. 10, ll. 20-21}**.

Independent claim 39 reads as follows:

60. A method of treating a subject in need of either symptomatic or prophylactic treatment **{p. 39, ll. 28-29}** with a sterile particulate fluticasone composition **{p. 10, ll. 20-21}** comprising the step of administering to the subject an effective amount of the sterile particulate fluticasone composition **{p. 10, ll. 20-21}** sterilized by passing the composition through a 0.2μm filter **{p. 20, ll. 7-9}**, wherein the sterile particulate fluticasone composition **{p. 10, ll. 20-21}** comprises particles of fluticasone or a salt thereof **{p. 29, ll. 5-6}** and at least one surface stabilizer **{p. 28, ll. 12-13}**, wherein the fluticasone particles have an effective average particle size of less than 150 nm **{p. 8, ll. 16-18; p. 19, ll. 23-29; p. 32, l. 25}**.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The rejections to be reviewed on appeal are the following:

1. Rejection of claims 17, 19-24, 28-44, 47, 49-61, 64-67, 69 and 71-81 under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,747,001 to Wiedmann et al. ("Wiedmann") in view of U.S. Patent No. 6,241,969 to Saidi et al. ("Saidi").

2. Rejection of claims 17, 19-24, 28-44, 47, 49-61, 64-67, 69 and 71-81 under 35 U.S.C. §103(a) for allegedly being obvious over PCT Publication No. WO 96/25918 by Wood et al. ("Wood") in view of Saidi, and in further view of U.S. Patent Application Publication No. US 2003/0073676 by Biggadike et al. ("Biggadike").

ARGUMENT

Pursuant to 37 C.F.R. §41.39, Appellants respond to certain comments made in the Examiner's Answer dated July 8, 2010 ("the Answer"). All arguments submitted in the Appeal Brief but not repeated are incorporated herewith by reference.

Appellants' comments in response to the Examiner's alleged "related appeals" are presented in the foregoing section "Related Appeals and Interferences."

A. The rejection rationale is informed by Appellants' claimed invention as well as impermissible hindsight.

The Examiner appears to argue that because Wiedmann discloses a beclomethasone composition having a particle size of less than 100 nm in one embodiment, one skilled in the art would find it obvious to sterilize the composition by filtration through a 0.2 micron filter. *See* the Answer, the paragraph bridging pages 13 and 14.

Wiedmann relates to an aerosol comprising droplets of a dispersion of beclomethasone nanoparticles having an effective average particle size of less than 400 nm. *See* the abstract, and column 10, lines 24-28. Wiedmann further describes the particle size of the nanoparticulate beclomethasone composition as follows:

> *...In preferred embodiments, the effective average particle size is less than about 300 nm and more preferably less than about 250 nm. In some embodiments, an effective average particle size of less than about 100 nm has been achieved...*

Wiedmann, column 10, lines 28-32.

The Examiner asserts obviousness on the ground that Wiedmann's composition has a particle size "as small as 100 nm, small enough to be sterile filtered through a 0.2 μm filter." The Answer, page 15, lines 2-6.

First, the Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex* ("the Updated Guidelines," *Federal Register* 75 (169): 53643-53660, September 1, 2010) sets forth that "[e]ven where a general method that ***could have*** been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown." The Updated Guidelines, at page 53646, the paragraph bridging the middle column and the right column; emphasis added. Therefore, the question to be addressed in the obviousness rejection is not whether one of ordinary skill in the art "could have" filtered Wiedmann's compositions having a particle size less than 100 nm, but rather whether one "would have" any reason to do so in view of Saidi's teaching.

The Updated Guidelines further state that when the proposed modification amounts to extra work and greater expense for no apparent reason, the claimed invention is nonobvious over prior art. In the present case, Wiedmann has expressed no desire to sterilize the composition by passing it through a 0.2 μm filter. The Examiner attempts to rely on Saidi for the alleged teaching of sterile filtration. However, Saidi resolves the sterile filtration issue of a fluticasone composition by ***dissolving*** fluticasone in TPGS and then passing the solution through a filter. *See* Saidi, column 5, lines 34-35, 49-52; and column 9 line 65 through column 11, line 2. To substantiate the rejection, the Examiner made a series of logic leaps, none of which is supported by the teachings of the cited art. For example, one skilled in the art would first have to undertake solubilizing Weidmann's ***dispersion comprising solid particles of fluticasone*** (because only solubilized fluticasone is sterilized in Saidi). Then, one would have to re-solidify the fluticasone to obtain a sterilized ***dispersion comprising solid particles of fluticasone***. It is unclear why one of ordinary skill in the art would submit to such an onerous process when alternatives to sterilizing dispersions exist. The rejection rationale requires one skilled in the art to conduct convoluted, extra work and expense, for no apparent reason. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness by articulating a reason to combine the cited references.

Second, when the teaching of Wiedmann is taken as a whole, one skilled in the art would not attempt to sterilize Wiedmann's composition by passing it through a 0.2 μm filter. This is because Wiedmann discloses, in general, a particle size of less than 400 nm but has no specific reason to reduce the particle size to less than 100 nm. The working example of Wiedmann demonstrates a nanoparticulate beclomethasone diproprionate composition having "a particle size distribution of 0.26 ± 0.13 μm" (column 12, lines 29-31). In other words, one skilled in the art would not have any reason to filter a composition having a particle size distribution of between 0.13 μm and 0.39 μm because a significant amount of the beclomethsaone diproprionate particles would be retained on the filter rather than passing through the filter.

By the same token, another primary reference cited by the Examiner, Wood, discloses in general a composition having a particle size of less than 1000 nm, preferably less than 400 nm or less than 300 nm. *See* page 16, last paragraph. Wood further describes "[i]n some embodiments, an effective average particle size of less than about 100 nm has been achieved." *Id.* Because Wood discloses a laundry list of active agents at pages 4 and 5, it is unclear what active agent can be reduced to less than 100 nm. Similar to Wiedmann, Wood fails to disclose sterilizing the composition by passing it through a 0.2 μm filter. Therefore, as stated above, Saidi is relied upon for this teaching. As argued above, one would not attempt the convoluted solubilizing/re-solubilizing process of the particles in Wood to sterilize using the process in Saidi..

Accordingly, in the absence of any suggestion in the cited art to combine the teachings of the primary reference and the secondary reference, the Examiner could have only based the rejection on impermissible hindsight using Appellants' claimed invention as a road map.

B. Wiedmann or Wood has no teaching or suggestion of sterile filtration.

The Examiner asserts that Wiedmann and Wood disclose several techniques, including microprecipitation, to separate and form nanoparticles. *See* the Answer, pages 16-17 and 18-19. As submitted in the Appeal Brief, the sterile filtration technique of the claimed invention entails

removing microorganisms from the composition. Sterile filtration is a sterilization technique, which is distinguishable from the macro-filtration or simple filtration disclosed by Wiedmann or Wood, which is a separation technique.

However, as admitted by the Examiner, the microprecipitation technique is a separation procedure which removes formed salt or heavy metal impurities rather than a sterilization procedure which removes microorganisms from the composition. *See* the Answer, page 16, line 11, through page 17, line 2; and page 18, line 14, through page 19, line 4. In other words, these techniques differ in removing different types of contaminants, heavy metals and salts or microorganisms. The Examiner overly generalizes and thereby equates different concepts by his comment that both techniques are used for "removal of contaminants" (the Answer, page 17, lines 2-3; and page 19, lines 4-5).

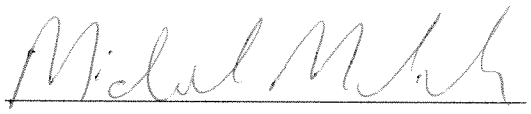
In view of the foregoing, Appellants respectfully request that the Board reverse the rejection in whole.

CONCLUSION

For the reasons discussed above, Appellants respectfully submit that all pending claims are in condition for allowance, and respectfully requests that the rejections be reversed in whole, and that the claims be allowed to issue.

Respectfully submitted,

Date: September 7, 2010

By 

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APPENDIX A: CLAIMS INVOLVED IN APPEAL

1. – 16. (Cancelled)

17. (Previously Presented) A sterile filterable dispersion comprising:

(a) an aqueous dispersion medium;

(b) fluticasone particles sufficiently small to pass through a 0.2μm filter, and have a phase selected from the group consisting of a crystalline phase, an amorphous phase, and a semi-crystalline phase; and

(c) at least one surface stabilizer adsorbed on the surface of the fluticasone particles, wherein the dispersion is sterilized by filtration through a 0.2 μm filter.

18. (Cancelled)

19. (Previously Presented) The sterile filterable fluticasone dispersion of claim 17, wherein the surface stabilizer is tyloxapol.

20. (Previously Presented) The sterile filterable fluticasone dispersion of claim 17, wherein at least 99.9% of the fluticasone particles have a particle size of less than 200 nm.

21. (Previously Presented) The sterile filterable fluticasone dispersion of claim 17, wherein at least 90% of the fluticasone particles have a particle size of less than 130 nm.

22. (Previously Presented) A sterile filterable fluticasone composition comprising:

(a) particles of fluticasone or a salt thereof, wherein at least 99.9% of the fluticasone particles have a particle size of less than 200 nm; and

(b) tyloxapol as a surface stabilizer,

wherein the composition is sterilized by filtration through a 0.2 μm filter.

23. (Previously Presented) A nanoparticulate fluticasone composition comprising:

(a) particles of fluticasone or a salt thereof, wherein the fluticasone particles have an effective average particle size of less than 150 nm; and

(b) at least one surface stabilizer adsorbed on the surface of the fluticasone particles, wherein the composition is sterilized by filtration through a 0.2μm filter.

24. (Previously Presented) The composition of claim 23, wherein the effective average particle size of the fluticasone particles is selected from the group consisting of less than 140 nm, less than 130 nm, less than 120 nm, less than 110 nm, less than 100 nm, less than 90 nm, less than 80 nm, less than 70 nm, less than 60 nm, and less than 50 nm.

25.-26. (Cancelled)

27. (Original) The composition of claim 23 formulated for administration selected from the group consisting of oral, pulmonary, rectal, opthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

28. (Original) The composition of claim 23 further comprising one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

29. (Previously Presented) The composition of claim 28, wherein the fluticasone particles are present in the composition in an amount selected from the group consisting of from 99.5% to 0.001%, from 95% to 0.1%, and from 90% to 0.5%, by weight, based on the total combined dry weight of the fluticasone and at least one surface stabilizer, not including other excipients.

30. (Previously Presented) The composition of claim 28, wherein the at least one surface stabilizer is present in an amount selected from the group consisting of from 0.5% to 99.999%, from 5.0% to 99.9%, and from 10% to 99.5%, by weight, based on the total combined dry weight of the fluticasone and at least one surface stabilizer, not including other excipients.

31. (Original) The composition of claim 23, comprising at least two surface stabilizers.

32. (Original) The composition of claim 23, wherein the surface stabilizer is selected from the group consisting of an anionic surface stabilizer, a cationic surface stabilizer, a zwitterionic surface stabilizer, and an ionic surface stabilizer.

33. (Previously Presented) The composition of claim 32, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl β-D-glucopyranoside; n-decyl β-D-maltopyranoside; n-dodecyl β-D-glucopyranoside; n-dodecyl β-D-maltoside; heptanoyl-N-methylglucamide; n-heptyl-β-D-glucopyranoside; n-heptyl β-D-thioglucoside; n-hexyl β-D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl β-D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl-β-D-glucopyranoside; octyl β-D-thioglucopyranoside; lysozyme, PEG-derivatized phospholipid, PEG-derivatized cholesterol, PEG-derivatized cholesterol, PEG-derivatized vitamin A, PEG-derivatized vitamin E, and random copolymers of vinyl acetate and vinyl pyrrolidone.

34. (Previously Presented) The composition of claim 32, wherein the at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, a phospholipid, zwitterionic stabilizers, poly-n-methylpyridinium, anthryul pyridinium chloride, chitosan, polylysine, polyvinylimidazole, polybrene, polymethylmethacrylate trimethylammoniumbromide bromide (PMMTMABr), hexyldesyltrimethylammonium bromide (HDMAB), polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, 1,2 Dipalmitoyl-sn-Glycero-3-Phosphoethanolamine-N-[Amino(Polyethylene Glycol)2000] (sodium salt), Poly(2-methacryloxyethyl trimethylammonium bromide), poloxamines, lysozyme, alginic acid, carrageenan, and nonionic, high molecular weight, water-soluble poly(ethylene oxide) polymers.

35. (Previously Presented) The composition of claim 32, wherein the at least one cationic surface stabilizer is selected from the group consisting of cationic lipids, sulfonium, phosphonium, quarternary ammonium compounds, stearyltrimethylammonium chloride, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium bromide, C_{12-15}dimethyl hydroxyethyl ammonium chloride, C_{12-15}dimethyl hydroxyethyl ammonium bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl $(ethenoxy)_4$ ammonium chloride, lauryl dimethyl $(ethenoxy)_4$ ammonium bromide, N-alkyl (C_{12-18})dimethylbenzyl ammonium chloride, N-alkyl (C_{14-18})dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C_{12-14}) dimethyl 1-napthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts,

lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C_{12-14}) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C_{12}, C_{15}, C_{17} trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, polyquaternium 10, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, quaternized ammonium salt polymers, imidazoline, alkyl pyridinium salts, amines, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

36. (Previously Presented) The composition of claim 35, wherein the amine is selected from the group consisting of alkylamines, dialkylamines, alkanolamines, polyethylenepolyamines, N,N-dialkylaminoalkyl acrylates, vinyl pyridine, amine salts, lauryl amine acetate, stearyl amine acetate, alkylpyridinium salt, alkylimidazolium salt, amine oxides, and imide azolinium salts.

37. (Original) The composition of claim 34, wherein the cationic surface stabilizer is a nonpolymeric compound selected from the group consisting of benzalkonium chloride, a carbonium compound, a phosphonium compound, an oxonium compound, a halonium compound, a cationic organometallic compound, a quarternary phosphorous compound, a pyridinium compound, an anilinium compound, an ammonium compound, a hydroxylammonium

compound, a primary ammonium compound, a secondary ammonium compound, a tertiary ammonium compound, behenalkonium chloride, benzethonium chloride, cetylpyridinium chloride, behentrimonium chloride, lauralkonium chloride, cetalkonium chloride, cetrimonium bromide, cetrimonium chloride, cethylamine hydrofluoride, chlorallylmethenamine chloride (Quaternium-15), distearyldimonium chloride (Quaternium-5), dodecyl dimethyl ethylbenzyl ammonium chloride(Quaternium-14), Quaternium-22, Quaternium-26, Quaternium-18 hectorite, dimethylaminoethylchloride hydrochloride, cysteine hydrochloride, diethanolammonium POE (10) oletyl ether phosphate, diethanolammonium POE (3)oleyl ether phosphate, tallow alkonium chloride, dimethyl dioctadecylammoniumbentonite, stearalkonium chloride, domiphen bromide, denatonium benzoate, myristalkonium chloride, laurtrimonium chloride, ethylenediamine dihydrochloride, guanidine hydrochloride, pyridoxine HCl, iofetamine hydrochloride, meglumine hydrochloride, methylbenzethonium chloride, myrtrimonium bromide, oleyltrimonium chloride, polyquaternium-1, procainehydrochloride, cocobetaine, stearalkonium bentonite, stearalkoniumhectonite, stearyl trihydroxyethyl propylenediamine dihydrofluoride, tallowtrimonium chloride, and hexadecyltrimethyl ammonium bromide.

38. (Original) The composition according to any of claims 32, 34, 35, 36, or 37, wherein the composition is bioadhesive.

39. (Previously Presented) A method of making a fluticasone composition comprising:

contacting fluticasone or a salt thereof with at least one surface stabilizer for a time and under conditions sufficient to provide a particulate fluticasone composition comprising particles of fluticasone having an effective average particle size of less than 150 nm; and

passing the particulate fluticasone composition through a 0.2μm filter to sterilize the particulate fluticasone composition.

40. (Original) The method of claim 39, wherein said contacting comprises grinding.

41. (Original) The method of claim 40, wherein said grinding comprises wet grinding.

42. (Original) The method of claim 39, wherein said contacting comprises homogenizing.

43. (Original) The method of claim 39, wherein said contacting comprises:

(a) dissolving the fluticasone particles in a solvent;

(b) adding the resulting fluticasone solution to a solution comprising at least one surface stabilizer; and

(c) precipitating the solubilized fluticasone having at least one surface stabilizer by the addition thereto of a non-solvent.

44. (Previously Presented) The method of claim 39, wherein the effective average particle size of the fluticasone particles is selected from the group consisting of less than 140 nm, less than 130 nm, less than 120 nm, less than 110 nm, less than 100 nm, less than 90 nm, less than 80 nm, less than 70 nm, less than 60 nm, and less than 50 nm.

45.-46. (Cancelled)

47. (Previously Presented) The method of claim 39, wherein the fluticasone has a phase selected from the group consisting of a crystalline phase, an amorphous phase, and a semi-crystalline phase.

48. (Previously Presented) The method of claim 39 further comprising formulating the particulate fluticasone composition into a dosage form suitable for administration to a patient, wherein the route of administration is selected from the group consisting of oral, pulmonary, rectal, opthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

49. (Previously Presented) The method of claim 39, wherein the contacting step further comprises contacting the fluticasone with one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

50. (Previously Presented) The method of claim 49, wherein the fluticasone particles are present in the particulate fluticasone composition an amount selected from the group consisting of from 99.5% to 0.001%, from 95% to 0.1%, and from 90% to 0.5%, by weight, based on the total combined dry weight of the fluticasone particles and the at least one surface stabilizer, not including other excipients.

51. (Previously Presented) The method of claim 49, wherein the at least one surface stabilizer is present in the particulate fluticasone composition in an amount selected from the group consisting of from 0.5% to 99.999%, from 5.0% to 99.9%, and from 10% to 99.5%, by weight, based on the total combined dry weight of the fluticasone and the at least one surface stabilizer, not including other excipients.

52. (Original) The method of claim 39, wherein the fluticasone composition comprises at least two surface stabilizers.

53. (Original) The method of claim 39, wherein the surface stabilizer is selected from the group consisting of an anionic surface stabilizer, a cationic surface stabilizer, a zwitterionic surface stabilizer, and an ionic surface stabilizer.

54. (Previously Presented) The method of claim 53, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate,

carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl β-D-glucopyranoside; n-decyl β-D-maltopyranoside; n-dodecyl β-D-glucopyranoside; n-dodecyl β-D-maltoside; heptanoyl-N-methylglucamide; n-heptyl-β-D-glucopyranoside; n-heptyl β-D-thioglucoside; n-hexyl β-D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl β-D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl-β-D-glucopyranoside; octyl β-D-thioglucopyranoside; lysozyme, PEG-derivatized phospholipid, PEG-derivatized cholesterol, PEG-derivatized cholesterol, PEG-derivatized vitamin A, PEG-derivatized vitamin E, and random copolymers of vinyl acetate and vinyl pyrrolidone.

55. (Previously Presented) The method of claim 53, wherein the at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, a phospholipid, zwitterionic stabilizers, poly-n-methylpyridinium, anthryul pyridinium chloride, chitosan, polylysine, polyvinylimidazole, polybrene, polymethylmethacrylate trimethylammoniumbromide bromide (PMMTMABr), hexyldesyltrimethylammonium bromide (HDMAB), polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, 1,2 Dipalmitoyl-sn-Glycero-3-Phosphoethanolamine-N-[Amino(Polyethylene Glycol)2000] (sodium salt), Poly(2-methacryloxyethyl trimethylammonium bromide), poloxamines, lysozyme, alginic acid, carrageenan, and nonionic, high molecular weight, water-soluble poly(ethylene oxide) polymers.

56. (Previously Presented) The method of claim 53, wherein the at least one cationic surface stabilizer is selected from the group consisting of cationic lipids, sulfonium,

phosphonium, quarternary ammonium compounds, stearyltrimethylammonium chloride, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium bromide, C_{12-15}dimethyl hydroxyethyl ammonium chloride, C_{12-15}dimethyl hydroxyethyl ammonium bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl $(ethenoxy)_4$ ammonium chloride, lauryl dimethyl $(ethenoxy)_4$ ammonium bromide, N-alkyl (C_{12-18})dimethylbenzyl ammonium chloride, N-alkyl (C_{14-18})dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C_{12-14}) dimethyl 1-napthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C_{12-14}) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C_{12}, C_{15}, C_{17} trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, polyquaternium 10, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl

pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines quaternized ammonium salt polymers, imidazoline, alkyl pyridinium salts, amines, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

57. (Previously Presented) The method of claim 56, wherein the amine is selected from the group consisting of alkylamines, dialkylamines, alkanolamines, polyethylenepolyamines, N,N-dialkylaminoalkyl acrylates, vinyl pyridine, amine salts, lauryl amine acetate, stearyl amine acetate, alkylpyridinium salt, alkylimidazolium salt, amine oxides, and imide azolinium salts.

58. (Original) The method of claim 55, wherein the cationic surface stabilizer is a nonpolymeric compound selected from the group consisting of benzalkonium chloride, a carbonium compound, a phosphonium compound, an oxonium compound, a halonium compound, a cationic organometallic compound, a quarternary phosphorous compound, a pyridinium compound, an anilinium compound, an ammonium compound, a hydroxylammonium compound, a primary ammonium compound, a secondary ammonium compound, a tertiary ammonium compound, behenalkonium chloride, benzethonium chloride, cetylpyridinium chloride, behentrimonium chloride, lauralkonium chloride, cetalkonium chloride, cetrimonium bromide, cetrimonium chloride, cethylamine hydrofluoride, chlorallylmethenamine chloride (Quaternium-15), distearyldimonium chloride (Quaternium-5), dodecyl dimethyl ethylbenzyl ammonium chloride(Quaternium-14), Quaternium-22, Quaternium-26, Quaternium-18 hectorite, dimethylaminoethylchloride hydrochloride, cysteine hydrochloride, diethanolammonium POE (10) oletyl ether phosphate, diethanolammonium POE (3)oleyl ether phosphate, tallow alkonium chloride, dimethyl dioctadecylammoniumbentonite, stearalkonium chloride, domiphen bromide, denatonium benzoate, myristalkonium chloride, laurtrimonium chloride, ethylenediamine dihydrochloride, guanidine hydrochloride, pyridoxine HCl, iofetamine hydrochloride, meglumine hydrochloride, methylbenzethonium chloride, myrtrimonium bromide, oleyltrimonium chloride, polyquaternium-1, procainehydrochloride, cocobetaine, stearalkonium bentonite,

stearalkoniumhectonite, stearyl trihydroxyethyl propylenediamine dihydrofluoride, tallowtrimonium chloride, and hexadecyltrimethyl ammonium bromide.

59. (Original) The method according to any of claims 53, 55, 56, 57, or 58, wherein the fluticasone composition is bioadhesive.

60. (Previously Presented) A method of treating a subject in need of either symptomatic or prophylactic treatment with a sterile particulate fluticasone composition comprising the step of administering to the subject an effective amount of the sterile particulate fluticasone composition sterilized by passing the composition through a 0.2μm filter, wherein the sterile particulate fluticasone composition comprises particles of fluticasone or a salt thereof and at least one surface stabilizer, wherein the fluticasone particles have an effective average particle size of less than 150 nm.

61. (Previously Presented) The method of claim 60, wherein the effective average particle size of the fluticasone particles is selected from the group consisting of less than 140 nm, less than 130 nm, less than 120 nm, less than 110 nm, less than 100 nm, less than 90 nm, less than 80 nm, less than 70 nm, less than 60 nm, and less than 50 nm.

62.-63. (Cancelled)

64. (Previously Presented) The method of claim 60, wherein the subject has a condition selected from the group consisting of a respiratory related illness, inflammatory airways diseases, obstructive airways diseases, Whipple's disease, AIDS related pneumonia, asthma, emphysema, respiratory distress syndrome, chronic obstructive pulmonary disease, chronic bronchitus, cystic fibrosis, pneumonia, acquired immune deficiency syndrome related respiratory disorders, seasonal rhinitis, perennial rhinitis, seasonal allergic rhinitis, seasonal nonallergic rhinitis, perennial allergic rhinitis, perennial nonallergic rhinitis, and skin conditions treatable with topical corticosteroids.

65. (Original) The method of claim 64, wherein the subject has a condition selected from the group consisting of intrinsic (non-allergic) asthma, extrinsic (allergic) asthma, wheezy-infant syndrome, acute lung injury, acute respiratory distress syndrome, chronic obstructive pulmonary disease, chronic obstructive airways disease, chronic obstructive lung disease, chronic bronchitis, emphysema, bronchiectasis, exacerbation of airways hyperreactivity consequent to other drug therapy, and pneumoconiosis.

66. (Previously Presented) The method of claim 60, wherein the prophylactic efficacy of the treatment is evidenced by one or more characteristics selected from the group consisting of reduced frequency of symptomatic attack, reduced severity of symptomatic attack, improvement in lung function, improved airways hyperreactivity, and a reduced requirement for other symptomatic therapy.

67. (Original) The method of claim 60, wherein the subject is a human.

68. (Cancelled)

69. (Previously Presented) The method of claim 60, wherein the fluticasone has a phase selected from the group consisting of a crystalline phase, an amorphous phase and a semi-crystalline phase.

70. (Previously Presented) The method of claim 60, wherein the sterile particulate fluticasone composition is formulated into a dosage form suitable for administration to a patient, wherein said route of administration is selected from the group consisting of oral, pulmonary, rectal, opthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

71. (Original) The method of claim 60, wherein the fluticasone composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

72. (Previously Presented) The method of claim 71, wherein the particulate fluticasone is present in the sterile particulate fluticasone composition in an amount selected from the group consisting of from 99.5% to 0.001%, from 95% to 0.1%, and from 90% to 0.5%, by weight, based on the total combined dry weight of the fluticasone and at least one surface stabilizer, not including other excipients.

73. (Previously Presented) The method of claim 71, wherein the at least one surface stabilizer is present in the sterile particulate fluticasone composition in an amount selected from the group consisting of from 0.5% to 99.999%, from 5.0% to 99.9%, and from 10% to 99.5%, by weight, based on the total combined dry weight of the fluticasone and at least one surface stabilizer, not including other excipients.

74. (Previously Presented) The method of claim 60, wherein the sterile particulate fluticasone composition comprises at least two surface stabilizers.

75. (Original) The method of claim 60, wherein the surface stabilizer is selected from the group consisting of an anionic surface stabilizer, a cationic surface stabilizer, a zwitterionic surface stabilizer, and an ionic surface stabilizer.

76. (Previously Presented) The method of claim 75, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol,

polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl β-D-glucopyranoside; n-decyl β-D-maltopyranoside; n-dodecyl β-D-glucopyranoside; n-dodecyl β-D-maltoside; heptanoyl-N-methylglucamide; n-heptyl-β-D-glucopyranoside; n-heptyl β-D-thioglucoside; n-hexyl β-D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl β-D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl-β-D-glucopyranoside; octyl β-D-thioglucopyranoside; lysozyme, PEG-derivatized phospholipid, PEG-derivatized cholesterol, PEG-derivatized cholesterol, PEG-derivatized vitamin A, PEG-derivatized vitamin E, and random copolymers of vinyl acetate and vinyl pyrrolidone.

77. (Previously Presented) The method of claim 75, wherein the at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, a phospholipid, zwitterionic stabilizers, poly-n-methylpyridinium, anthryul pyridinium chloride, chitosan, polylysine, polyvinylimidazole, polybrene, polymethylmethacrylate trimethylammoniumbromide bromide (PMMTMABr), hexyldesyltrimethylammonium bromide (HDMAB), polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, 1,2 Dipalmitoyl-sn-Glycero-3-Phosphoethanolamine-N-[Amino(Polyethylene Glycol)2000] (sodium salt), Poly(2-methacryloxyethyl trimethylammonium bromide), poloxamines, lysozyme, alginic acid, carrageenan, and nonionic, high molecular weight, watersoluble poly(ethylene oxide) polymers.

78. (Previously Presented) The method of claim 75, wherein the at least one cationic surface stabilizer is selected from the group consisting of cationic lipids, sulfonium, phosphonium, quarternary ammonium compounds, stearyltrimethylammonium chloride, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut

trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium bromide, C_{12-15}dimethyl hydroxyethyl ammonium chloride, C_{12-15}dimethyl hydroxyethyl ammonium bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl $(ethenoxy)_4$ ammonium chloride, lauryl dimethyl $(ethenoxy)_4$ ammonium bromide, N-alkyl (C_{12-18})dimethylbenzyl ammonium chloride, N-alkyl (C_{14-18})dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C_{12-14}) dimethyl 1-napthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C_{12-14}) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C_{12}, C_{15}, C_{17} trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, polyquaternium 10, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, quaternized

ammonium salt polymers, imidazoline, alkyl pyridinium salts, amines, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

79. (Previously Presented) The method of claim 78, wherein the amine is selected from the group consisting of alkylamines, dialkylamines, alkanolamines, polyethylenepolyamines, N,N-dialkylaminoalkyl acrylates, vinyl pyridine, amine salts, lauryl amine acetate, stearyl amine acetate, alkylpyridinium salt, alkylimidazolium salt, amine oxides, and imide azolinium salts.

80. (Original) The method of claim 77, wherein the cationic surface stabilizer is a nonpolymeric compound selected from the group consisting of benzalkonium chloride, a carbonium compound, a phosphonium compound, an oxonium compound, a halonium compound, a cationic organometallic compound, a quarternary phosphorous compound, a pyridinium compound, an anilinium compound, an ammonium compound, a hydroxylammonium compound, a primary ammonium compound, a secondary ammonium compound, a tertiary ammonium compound, behenalkonium chloride, benzethonium chloride, cetylpyridinium chloride, behentrimonium chloride, lauralkonium chloride, cetalkonium chloride, cetrimonium bromide, cetrimonium chloride, cethylamine hydrofluoride, chlorallylmethenamine chloride (Quaternium-15), distearyldimonium chloride (Quaternium-5), dodecyl dimethyl ethylbenzyl ammonium chloride(Quaternium-14), Quaternium-22, Quaternium-26, Quaternium-18 hectorite, dimethylaminoethylchloride hydrochloride, cysteine hydrochloride, diethanolammonium POE (10) oletyl ether phosphate, diethanolammonium POE (3)oleyl ether phosphate, tallow alkonium chloride, dimethyl dioctadecylammoniumbentonite, stearalkonium chloride, domiphen bromide, denatonium benzoate, myristalkonium chloride, laurtrimonium chloride, ethylenediamine dihydrochloride, guanidine hydrochloride, pyridoxine HCl, iofetamine hydrochloride, meglumine hydrochloride, methylbenzethonium chloride, myrtrimonium bromide, oleyltrimonium chloride, polyquaternium-1, procainehydrochloride, cocobetaine, stearalkonium bentonite,

stearalkoniumhectonite, stearyl trihydroxyethyl propylenediamine dihydrofluoride, tallowtrimonium chloride, and hexadecyltrimethyl ammonium bromide.

81. (Original) The method according to any of claims 75, 77, 78, 79, or 80, wherein the composition is bioadhesive.

82.–99. (Cancelled)

APPENDIX B: RELATED PROCEEDINGS

No related proceedings are pending.